

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

NEW ENGLAND ANTI-VIVISECTION *
SOCIETY, *et al.*, *

Plaintiffs, *

Case No. 8:20-cv-02004-JRR

v. *

GOLDENTYER, *et al.*, *

Defendants. *

* * * * *

MEMORANDUM OPINION

I. INTRODUCTION

Plaintiffs Rise for Animals (“Rise”)¹ and Animal Legal Defense Fund (“ALDF”) are nonprofit organizations focused on advancing the interests of animals. (ECF No. 1 ¶ 6.) Specifically, Rise seeks to end the suffering of nonhuman primates used in research, and works to educate the public, lawmakers, and others to that end. *Id.* ¶ 6. Similarly, ALDF engages in campaigns to bring public awareness to what it views as the failures of laboratories to provide proper care for their research subject primates. *Id.* ¶ 15.

Rise and ALDF bring this action pursuant to the Administrative Procedure Act (“APA”) against Defendants Elizabeth Goldentyer, Acting Deputy Administrator for Animal Care at the Animal Plant and Health Inspection Service (“APHIS”), and Sonny Perdue, Secretary of the United States Department of Agriculture (“USDA”).² Plaintiffs seek judicial review of APHIS’s

¹ Rise for Animals was formerly called the New England Anti-Vivisection Society. (ECF No. 35-1 at 1 n.1.)

² The USDA is the parent agency of APHIS. The USDA and APHIS are together referred to herein as the “Agency.”

refusal to upgrade the standards for the psychological well-being of nonhuman primates used in laboratory research.

Pending before the court are the parties' cross motions for summary judgment (ECF Nos. 35 and 38, Pls. Motion and Defs. Motion, respectively). The court has reviewed the parties' submissions and no hearing is necessary. Local Rule 105.6 (D. Md. 2021). For the reasons set forth herein, Plaintiffs' Motion will be granted and Defendants' Motion will be denied.

II. BACKGROUND

A. Statutory and Regulatory Background

1. Animal Welfare Act of 1966

In 1966, Congress enacted the Animal Welfare Act ("AWA") to "[e]nsure that animals intended for use in research facilities . . . are provided humane care and treatment." 7 U.S.C. § 2131(1). The AWA "authorizes the Secretary of Agriculture to promulgate standards and other requirements governing the humane handling, housing, care, treatment, and transportation of certain animals by dealers, exhibitors, and other regulated entities." 64 Fed. Reg. 38145 (July 15, 1999). The Secretary of Agriculture delegated responsibility to APHIS to enforce the AWA. *Id.*

2. AWA Amendment

In 1985, Congress recognized that nonhuman primates have psychological and social needs that are critical to their well-being and acknowledged that the "[c]urrent standards leave too much room for shoddy care and inhumane treatment." 131 Cong. Rec. 22257 (Aug. 1, 1985) (statement of Sen. Chafee). Further, Congress explained stricter standards were required to protect animals involved in research and experiments. 131 Cong. Rec. 22257 (Aug. 1, 1985).

Subsequently, in 1985, Congress passed the Improved Standards for Laboratory Animals Act ("ISLAA"), amending AWA. Pub. L. No. 99-198, 99 Stat. 1645 (1985). ISLAA amended

AWA to “ensure that animals necessary for research receive fair and humane treatment, and that their discomfort is kept to an absolute minimum,” while also recognizing that “animal research is essential to the progress of efforts to protect human health.” 131 Cong. Rec. 29274 (Aug. 1, 1985) (statement of Sen. Moynihan). ISLAA requires the Secretary of the USDA to promulgate standards that “include minimum requirements . . . for a physical environment adequate to promote the psychological well-being of primates.” 7 U.S.C. § 2143(a)(2)(B). ISLAA further provides that: “[t]he Secretary shall require each research facility to show upon inspection, and to report at least annually, that the provisions of this Act [7 USCS §§ 2131, *et seq.*] are being followed and that professionally acceptable standards governing the care, treatment, and use of animals are being followed by the research facility during actual research or experimentation.” *Id.* § 2143(a)(7)(A). Finally, with respect to investigations and inspections involving research facilities, “[t]he Secretary shall inspect each research facility at least once each year and, in the case of deficiencies or deviations from the standards promulgated under this Act, shall conduct such follow-up inspections as may be necessary until all deficiencies or deviations from such standards are corrected.” *Id.* § 2146(a).

3. USDA Regulation

In 1991, the USDA promulgated a regulation to implement ISLAA, which provides in relevant part:

Dealers, exhibitors, and research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates. The plan must be in accordance with the currently accepted professional standards as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian. This plan must be made available to APHIS [Animal and Plant Health Inspection Service] upon request, and, in the case of research facilities, to officials of any pertinent funding agency.

56 Fed. Reg. 6426 (1991), *codified at* 9 C.F.R. § 3.81. The regulation further requires that each plan address the following topics: (1) “the social needs of nonhuman primates of species known to exist in social groups in nature;” (2) “[e]nvironmental enrichment, [such that] [t]he physical environment in the primary enclosures must be enriched by providing means of expressing noninjurious species-typical activities;” (3) special conditions for certain types of primates, including infants and young nonhuman primates; and (4) the use of restraint devices. *Id.* §§ 3.81(a)-(d).

B. Procedural Background of the Parties’ Dispute

Pursuant to the APA, the public can engage in an agency’s rulemaking agenda. 5 U.S.C. § 553(e). On May 7, 2014, Plaintiffs submitted a petition for rulemaking to the USDA (the “Petition”) requesting the USDA “to exercise its authority under [AWA] to promulgate clear standards and definitions to promote the psychological well-being and appropriate ethological environments for primates used in research.” (ECF No. 38-3 at 3.) Plaintiffs posited that the current regulation, 9 C.F.R. § 3.81, “is so vague that it lacks any enforceable definition of how to evaluate if such a plan is actually effectively designed or implemented in a way that promotes the primates’ psychological well-being.” *Id.*

The Petition requested the following relief:

- 1) Include in AWA implementing regulations the [National Institutes of Health “NIH”]-accepted recommendations for ethologically appropriate environments for chimpanzees as accepted by NIH;
- 2) Adopt clear regulations for ethologically appropriate environments for all primates using NIH’s recommendations for such environments for chimpanzees as a baseline, with species-specific modifications for other primates, and;

3) Adopt regulations for determining how and when chimpanzees and other primates exhibit psychological distress and what “special attention” must be brought to bear to ameliorate these symptoms.

(ECF No. 38-3 at 48.)

The Petition cited and described adverse effects of research on the psychological well-being of nonhuman primates due to the lack of concrete standards, including learned helplessness, depression, infant mortality, excessive aggression, and post-traumatic stress disorder. (ECF No. 38-3 at 33, 41.) The Petition acknowledged that “the intent of the AWA was ‘to provide nonhuman primates with the opportunity to express a wide range of non-injurious, species appropriate behaviors’ and ‘to re-emphasize attention to adequate environmental conditions before abnormal behaviors develop.’” *Id.* at 42. The Petition also set forth Plaintiffs’ position that current regulations are not aligned with the intent of AWA. *Id.* at 41-42. Finally, Plaintiffs’ Petition cited the deleterious effects of chronic psychological stress of nonhuman primates on scientific research and results. *Id.* at 46.

Following publication of the Petition in the Federal Register for public review and comment, the USDA denied Plaintiffs’ Petition on October 10, 2019: “APHIS has determined that the existing regulations are sufficient, while providing flexibility to address species typical behavior along with the individual needs of the animal. The flexibilities allow regulated entities to evolve as the scientifically accepted standards change for ensuring animal welfare.” *Id.* at 3. (ECF No. 38-4 at 3, the “Agency Denial.”)

Plaintiffs filed the instant action on July 9, 2020, seeking judicial review of the Agency Denial. (ECF No. 1.) Plaintiffs request that the court issue an order: “(1) Declaring Defendants’ denial of Plaintiffs’ rulemaking petition is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, in violation of the APA, 5 U.S.C. § 706(2)(A); (2) Directing

Defendants to set aside their denial of Plaintiffs’ rulemaking petition; (3) Directing Defendants to render a new decision of Plaintiffs’ Rulemaking Petition consistent with this Court’s opinion, by a Court-ordered deadline; (4) Retaining jurisdiction of this matter until Defendants have fulfilled all statutory and Court-ordered obligations; (5) Awarding Plaintiffs their costs and reasonable attorneys’ fees incurred in bringing this action; and (6) Granting such other relief as the Court may deem just and proper.” (ECF No. 1 at 24-25.)

On October 19, 2020, Defendants filed a motion to dismiss challenging Plaintiffs’ Article III standing (ECF No. 7), which the court denied on September 29, 2021. (ECF No. 23.) Subsequently, Plaintiffs and Defendants filed the instant cross motions for summary judgment. (ECF Nos. 35 and 38.) Plaintiffs argue that the Agency’s denial of their Petition is arbitrary, capricious, and an abuse of discretion within the meaning of the APA at section 706(2)(A). (ECF No. 35-1 at 2.) Defendants counter that denial of the Petition “squarely falls within the USDA’s ‘broad discretion to choose how best to marshal its limited resources and personnel to carry out its delegated responsibilities.’” (ECF No. 38-1 at 2.)

III. STANDARD OF REVIEW

Rule 56 of the Federal Rules of Civil Procedure provides that a court “shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(a). “In a case involving review of a final agency action under the APA, however, the standard set forth in Rule 56(a) does not apply because of the limited role of a court in reviewing the administrative record.” *Ctr. for Sci. in the Pub. Interest v. Perdue*, 438 F. Supp. 3d 546, 556 (D. Md. 2020). “Under the APA, it is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record, whereas ‘the function of the district court is to determine whether or not as

a matter of law the evidence in the administrative record permitted the agency to make the decision it did.” *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.C. Cir. 2006) (quoting *Occidental Eng’g Co. v. INS*, 753 F.2d 766, 769-70 (9th Cir. 1985)). “Summary judgment thus serves as a mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and is otherwise consistent with the APA standard of review.” *Id.*

Maine v. Norton explains well the court’s administrative judicial review role on motions for summary judgment:

A Statement of Material Facts “as to which the moving party contends there is no genuine issue of material fact to be tried” serves limited purpose in cases brought pursuant to the APA because, as a general rule, all relevant facts are contained in the administrative record for such a case, and, as a result, there are no material facts in dispute. Under section 706 of the APA, the Court’s role is to determine whether the administrative agency was “arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law” in making the findings challenged by Plaintiffs. 5 U.S.C. § 706(2)(A). Because this case involves a challenge to a final administrative action, the Court’s review is limited to the administrative record. *See* 5 U.S.C. § 706; *Camp v. Pitts*, 411 U.S. 138, 142, 93 S. Ct. 1241, 1244, 36 L. Ed. 2d 106 (1973). Summary judgment is an appropriate procedure for resolving a challenge to a federal agency’s administrative decision when review is based upon the administrative record, even though the court does not employ the standard of review set forth in Rule 56. *See, e.g., Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44, 105 S. Ct. 1598, 1607, 84 L. Ed. 2d 643 (1985); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416, 91 S. Ct. 814, 28 L. Ed. 2d 136 (1971); *Richards v. I.N.S.*, 180 U.S. App. D.C. 314, 554 F.2d 1173, 1177 n.28 (D.C. Cir. 1977).

Maine v. Norton, 257 F. Supp. 2d 357, 363 (D. Me. 2003).

“It is a ‘foundational principle of administrative law’ that judicial review of agency action is limited to ‘the grounds that the agency invoked when it took the action.’” *Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020) (quoting *Michigan v. EPA*, 576 U. S. 743, 758 (2015)). The APA instructs the reviewing court to “hold unlawful and set aside

agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A).

As the Supreme Court explained in *Motor Vehicle Mfrs. Ass’n. of U.S., Inc. v. State Farm Mutual Auto. Ins. Co.*:

The scope of review under the “arbitrary and capricious” standard is narrow and a court is not to substitute its judgment for that of the agency. Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a “rational connection between the facts found and the choice made.” *Burlington Truck Lines v. United States*, 371 U.S. 156, 168, 83 S. Ct. 239, 245–246, 9 L.Ed.2d 207 (1962). In reviewing that explanation, we must “consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” *Bowman Transp. Inc. v. Arkansas-Best Freight System, supra*, 419 U.S., at 285, 95 S. Ct., at 442; *Citizens to Preserve Overton Park v. Volpe, supra*, 401 U.S., at 416, 91 S. Ct., at 823. Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt itself to make up for such deficiencies: “We may not supply a reasoned basis for the agency’s action that the agency itself has not given.” *SEC v. Chenery Corp.*, 332 U.S. 194, 196, 67 S. Ct. 1575, 1577, 91 L.Ed. 1995 (1947). We will, however, “uphold a decision of less than ideal clarity if the agency’s path may reasonably be discerned.” *Bowman Transp. Inc. v. Arkansas-Best Freight System, supra*, 419 U.S., at 286, 95 S. Ct., at 442.

Motor Vehicle Mfrs. Ass’n. of U.S., Inc. v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 43 (1983); *see also Roe v. Dep’t of Defense*, 947 F.3d 207, 220 (4th Cir. 2020) (same and explaining that “[a]lthough we accord substantial deference to an agency’s final action and presume it valid, ‘the arbitrary-and-capricious standard does not reduce judicial review to a rubber stamp of agency action.’”) (citations omitted).

Generally, “where the agency decides not to proceed with rulemaking, the ‘record’ for purposes of review need only include the petition for rulemaking, comments pro and con where deemed appropriate, and the agency’s explanation of its decision to reject the petition.” *WWHT, Inc. v. F.C.C.*, 656 F.2d 807, 817 (D.C. Cir. 1981). “The court’s task is to discern whether the relevant factors were considered and whether the ultimate decision reflects reasoned decision-making.” *Professional Drivers Council v. Bureau of Motor Carrier Safety*, 706 F.2d 1216, 1220 (D.C. Cir. 1983).³

IV. ADMINISTRATIVE RECORD

A. Public Comments

Plaintiffs’ Petition received over 10,000 public comments – 71% in favor of the Petition; 1% opposed; and 28% “did not address the petition issues.” (ECF No. 38-4 at 1.) Among the favorable comments was that of the Laboratory Primate Advocacy Group (“LPAG”), which agreed that the current standards were ineffective, allowed laboratory industries to self-regulate, and explained that “thousands of monkeys are traumatized each year because of lax standards.” (ECF No. 35-3; Ex. B.) Other commentators were individuals with personal experience working in research labs with primates: “[l]eaving the fate of animals in captivity in the individual hands of those to whom they serve without stringent oversight from regulatory agencies that clearly define what is expected in both physical and psychological wellbeing is negligent and a major contributor to unnecessary and prolonged suffering.” (ECF No. 35-5; Ex. D.) One primatologist opined: “[c]aged animals are under tremendous stress [t]hey are limited in space, the ability to interact,

³ Defendants take the position that denial of rulemaking is afforded a sort of super deference within the arbitrary and capricious standard of review. (ECF No. 38-1 at 11-12.) The parameters (not standard) of the review depend, of course, on the depth of the agency record. For example, where an agency has denied a petition for rulemaking, the agency record is rather limited. To the extent Defendants argues for some sort of sliding scale of scrutiny within the arbitrary and capricious standard, the court disagrees. *FCC v. Fox Television Stations*, 556 U.S. 502, 513 (2009).

and cues to understand their environment and above all, to predict their circumstances.” (ECF No. 35-6; Ex. E.)

B. The Agency Denial

The Agency Denial of October 10, 2019, provides in part:

...[O]ur experience administering and enforcing the welfare standards related to environmental enhancement to promote psychological well-being demonstrates such standards are, in fact, enforceable. Between 2007 and 2015, USDA cited facilities for issues including: insufficient recordkeeping; enrichment (no provision, poor condition, and not following the plan); and failure to address animals requiring special attention (singly housed animals, animals unable to see and hear other animals, and animals demonstrating symptoms of psychological distress).

With regard to your first request that we “include in AWA implementing regulations the NIH-accepted recommendations for ethologically appropriate environments for chimpanzees as accepted by NIH” APHIS is not making changes to the regulations. Under 9 C.F.R. Section 3.81, the regulations require entities “to develop, document, and follow an appropriate plan...” The regulation allows entities to develop and/or modify the plan to respond to ever-evolving strategies for ensuring animal welfare. APHIS inspectors evaluate a facilities’ compliance with the regulation during the inspection. They examine and document all areas of care and treatment that are covered under the AWA, including the plan. The inspector also observes the regulated animals; inspects facilities, including enclosure or housing materials space, and records. If the inspector observes that the facility is not in full compliance with the AWA requirements, he or she will explain all deficiencies and appropriately document the findings.

...APHIS has determined that the existing regulations are sufficient, while providing flexibility to address species typical behavior along with the individual needs of the animal. The flexibilities allow regulated entities to evolve as the scientifically accepted standards change for ensuring animal welfare.

... The existing AWA regulations contain adequate provisions to ensure the health and well-being of NHPs.

(Agency Denial, ECF No. 38-4.)

C. FOIA Request and Focused Inspections

At the time Plaintiffs filed this lawsuit they alleged in their Complaint: “on information and belief, APHIS also recently informed its inspectors of facilities accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (“AAALAC”) that they may choose which aspects of a particular facility they may wish to inspect.” (ECF No. 1 ¶ 70.) As a result, on June 17, 2020, Plaintiffs submitted a Freedom of Information Act (“FOIA”) request to the Agency “to obtain records that would demonstrate the actual inspection practices of the agency.” (ECF No. 35-1 at 17.)⁴

In response to the FOIA request, the Agency produced several internal agency documents.⁵ Among the documents were rules and requirements for conducting inspections. A USDA record titled “Annual Inspections for Research Facilities,” and marked “For Internal Use Only,” states:

In response to concerns from inspectors about workload, to promote the consistency of our inspections for all research facilities, and to allow us to focus our inspection resources on facilities that present greater risks to animal welfare, in February 2019, we issued guidance that made it mandatory (rather than discretionary) for inspectors to perform focused inspection at AAALAC-accredited research facilities unless the research facility requested a full inspection.

(ECF No. 39-1, “USDA Annual Inspections Document.”)⁶ A “focused inspection” is an annual inspection during which inspectors are prohibited from inspecting more than one of three facets of

⁴ Plaintiffs sought: “all records that would reveal instructions, directives, advice, suggestions, and any other guidance concerning how such inspections are to be conducted; relating to USDA and APHIS inspections of research laboratories; and all records containing any instructions, directives, advice, suggestions, and any other guidance to USDA and APHIS inspectors regarding inspections of research facilities that are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care” created or generated between January 1, 2017 and the date of the request, June 17, 2020.

⁵ On June 16, 2020, Plaintiffs filed action against the Agency for failure to comply with its production obligations under FOIA – *see Rise for Animals and Animal Legal Defense Fund v. APHIS and USDA*, Civil Case No. 20-3013, D. Md. 2020. The parties settled the dispute following production of responsive agency materials and the case was closed.

⁶ The parties stipulated that the court may consider this document as part of the agency record, as it was inadvertently omitted from the administrative record.

a subject facility: the animals, the facility, or the paperwork (or a sampling of same) – unless the research facility (not APHIS) requests a full inspection. (ECF No. 39-1; ECF No. 35-1 at 17-18; ECF No. 35-10, Ex. I.) According to the internal USDA Annual Inspections Document, not intended for publication, the Agency’s mandatory “focused inspection” practice may result in up to four years passing before an inspector lays eyes on a single research animal – and in years when animals are observed, it may be a “sampling” of the research animals, not a facility’s entire stock of subjects.

V. ANALYSIS⁷

Plaintiffs challenge the Agency Denial on four bases: (1) agency records contradict the factual basis presented in the Agency Denial; (2) the Agency Denial relies on non-binding suggestions; (3) the Agency Denial ignores science; and (4) the Agency Denial fails to address NIH’s conclusion that AWA standards are inadequate. (ECF No. 35-1 at 20, 22, 24, 27.) The Agency counters that denial of the Petition was not arbitrary and capricious because rulemaking denials require only “notice and an explanation,” which need not be exhaustive; and “the agency has done more than enough to ‘adequately explain[] the facts and policy concerns it relied on and [whether] . . . those facts have some basis in the record.’” (ECF No. 38-1 at 11, 18-19; quoting *Flyers Rts. Educ. Fund, Inc. v. U.S. Dept. of Transp.*, 957 F.3d 1359, 1363 (D.C. Cir. 2020), and *WildEarth Guardians v. EPA*, 751 F.3d 649, 653 (D.C. Cir. 2014).)

The Agency is correct that the arbitrary and capricious standard of review in a rulemaking setting is highly deferential to the Agency’s expertise, but the standard is not illusory.

While it is clear that the applicable scope of review of discretionary agency decisions not to promulgate certain rules can be found under

⁷ The Agency contends Plaintiffs lack standing on the basis that they have failed to allege a cognizable injury-in-fact. (ECF No. 38-1 at 12.) The Agency previously raised this argument and the court found Plaintiffs have Article III standing. (See Memorandum Opinion and Order at ECF Nos. 22 and 23.) The Agency does not raise new argument or legal authority to support its argument. The court, therefore, declines to revisit this issue.

section 10(e)(2) (A) of the APA, 5 U.S.C. § 706(2)(A), the parameters of the “arbitrary and capricious” standard of review will vary with the context of the case. In general, the “arbitrary and capricious” standard calls for a review that is “‘searching and careful,’ yet, in the last analysis, diffident and deferential.” The agency’s decision that the public interest does not require the promulgation of specific rules for the time being must be sustained “if it violates no law, is blessed with an articulated justification that makes a ‘rational connection between the facts found and the choice made,’ and follows upon a ‘hard look’ by the agency at the relevant issues.” The agency’s determination is essentially a legislative one, and the reviewing court should do no more than assure itself that the agency acted “in a manner calculated to negate the dangers of arbitrariness and irrationality”

WWHT, Inc. v. F.C.C., 656 F.2d 807, 817 (D.C. Cir. 1981) (internal citations omitted).

The court considers whether the Agency “adequately explained the facts and policy concerns it relied on and [whether] . . . those facts have some basis in the record.” *Id.*; *see also Motor Vehicle Mfrs. Ass’n. of U.S., Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (providing that “[n]ormally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”). While the court’s review is limited, “the arbitrary and capricious standard does not reduce judicial review to a rubber stamp of agency action.” *Friends of Back Bay v. U.S. Army Corps of Eng’rs*, 681 F.3d 581, 587 (4th Cir. 2012).⁸

⁸ If, upon review, the agency decision does not survive review, remand to the agency is the proper course of action in all but the rarest of cases. *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) (“If the record before the agency does not support the agency action, if the agency has not considered all relevant factors, or if the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it, the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation. The reviewing court is not generally empowered to conduct a *de novo* inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry.”); *see also United States Lines, Inc. v. Federal Maritime Commission*, 584 F.2d 519, 533 (D.C. Cir. 1978) (remanding to agency because “[w]e simply cannot determine whether the final agency decision reflects the rational outcome of the agency’s considerations of all relevant factors when we have no idea what factors or data were in fact considered by the agency”).

A. The Agency Record Contradicts the Agency Denial

Plaintiffs argue that “the agency offered an explanation for its decision that runs counter to the evidence before the agency.” (ECF No. 35-1 at 22.) Plaintiffs contend that the USDA Annual Inspections Document regarding “focused inspections” contradicts the Agency’s representations regarding its practice of “full inspections” set forth in the Agency Denial. *Id.* Plaintiffs argue that because the inspectors conduct “focused inspections” at AAACLA facilities, “the inspectors have no basis for determining whether ‘the facility is in full compliance with the AWA requirements.’” *Id.* at 22. Specifically, according to the USDA Annual Inspections Document, Agency inspectors are prohibited from conducting a standard, full annual inspection of any AAALAC-accredited research facility except where the facility requests a full inspection. In conducting “focused inspections,” inspectors may only conduct partial inspections which means that a “focused inspection” may not: examine all areas of care and treatment; observe regulated animals; or review pertinent facility plan documents and records as required by AWA and the ISLAA implementation regulation.

Under a “focused inspection” the inspector selects which facet of the facility to inspect and does not inspect all areas of the facility to ensure compliance with AWA standards in accordance with ISLAA; nor does the inspector, therefore, gather information regarding the adequacy of the AWA standard in practice. In the absence of full inspections, Plaintiffs urge, it necessarily follows that the Agency’s conclusion that current inspection procedures and AWA facility standards are adequate to fulfill the charge of AWA (vis-a-vis the health and well-being of nonhuman primates in a research setting) is baseless. And, Plaintiffs urge, that in the absence of industry-wide annual full inspections, the court cannot rely on the Agency’s conclusion that the primates receive the environment and attention required under AWA.

In contrast, as set forth above, the Agency Denial asserts: “The regulation allows entities to develop and/or modify the plan to respond to ever-evolving strategies for ensuring animal welfare. APHIS inspectors evaluate a facilities’ compliance with the regulation during the inspection. **They examine and document all areas of care and treatment that are covered under the AWA, including the plan. The inspector also observes the regulated animals; inspects facilities, including enclosure or housing materials space, and records.** If the inspector observes that the facility is not in full compliance with the AWA requirements, he or she will explain all deficiencies and appropriately document the findings.” (ECF No. 38-4; emphasis added by the court.)

1. Post-hoc Declaration of Dr. Elizabeth Goldentyer

To bridge the gulf, and apparent irreconcilable contradictions, between the USDA Annual Inspections Document (produced in response to Plaintiffs’ FOIA request and marked “For Internal Use Only”) and the Agency Denial, Defendants provide the Declaration of Dr. Elizabeth Goldentyer, the Deputy Administrator of the APHIS Animal Care program within the USDA. (ECF No. 38-5.)

The parties dispute whether the court may consider the Goldentyer Declaration given its role in judicial review of an agency decision. Plaintiffs argue that consideration of the Declaration is prohibited by law because the Agency is basically stuck with its own record, which, they argue, demonstrates that the Agency Denial is a farcical beard – because it is expressly contrary to the Agency’s practice in fact (per the internal USDA Annual Inspections Document). (ECF No. 39 at 10.) Defendants contend that the court may consider the Declaration because it provides only background or explanatory information to aid the court in understanding the agency record before it. (ECF No. 38-1 at 20.)

“[P]ost-hoc rationalizations . . . have traditionally been found to be an inadequate basis for review” and, at bottom, an agency “must defend its actions based on the reasons it gave when it acted.” *Roe v. United States DOD*, 947 F.3d 207, 220 (4th Cir. 2020); *Dep’t of Homeland Security v. Regents of Univ. of Calif.*, 140 S. Ct. 1891, 1909 (2020). “Courts may consider ‘affidavits not contained in the agency record . . . where there was such failure to explain administrative action as to frustrate effective judicial review.’” *Roe*, 947 F.3d at 221 (quoting *Dow AgroSciences, LLC v. National Marine Fisheries Service*, 707 F.3d 462, 468 (4th Cir. 2013)). Permissible “post-hoc materials must only provide ‘background information or evidence of whether all relevant factors were examined by an agency,’ or be ‘merely explanatory of the original record and . . . contain no new rationalizations.’” *Id.* (quoting *AT&T Info. Sys., Inc. v. Gen. Servs. Admin.*, 810 F.2d 1233, 1236 (D.C. Cir. 1987)). Essentially, “[i]f the reviewing court finds it necessary to go outside the administrative record, it should consider evidence relevant to the substantive merits of the agency action only for background information, [] or for the limited purposes of ascertaining whether the agency considered all the relevant factors or fully explicated its course of conduct or grounds of decision.” *Asarco, Inc. v. U.S. EPA*, 616 F.2d 1153, 1160 (9th Cir. 1980).⁹

Defendants assert that the Goldentyer Declaration “provides background information and is explanatory of the original record.” (ECF No. 38-1 at 20, n.5.) The court disagrees. While the Declaration does contain some semblance of background information, the Declaration cannot be plausibly described as “background” or “explanatory” in nature. In response to the Agency

⁹ In *Ardila Olivares v. Transportation Security Administration*, the court considered a post-hoc account because the declaration “contains ‘no new rationalizations’ [and] it is ‘merely explanatory of the original record,’ and thus admissible.” 819 F.3d 454, 464 (D.C. Cir. 2016). The court further explained that: “[a]lthough we find that the internal agency materials as illuminated by the [declaration], satisfy the requirements of § 555(e), we add a word of caution. In the future, agencies will be well advised to obey the explicit command of § 555(e), rather than counting on being able to salvage their actions later, after the losing party has been forced to seek redress in court.” *Id.* at 464-65.

Denial’s representation that APHIS inspectors “examine and document all areas of care and treatment that are covered under the AWA, including the plan. They examine and document all areas of care and treatment that are covered under the AWA, including the plan. The inspector also observes the regulated animals; inspects facilities, including enclosure or housing materials space, and records....”, Dr. Goldentyer’s Declaration provides:

In my denial letter, the sentence stating that USDA inspectors “examine and document all areas of care and treatment that are covered under the [Animal Welfare Act], including the plan” was not intended to mean that every single USDA inspection would look at every area of care and treatment regulated by the Animal Welfare Act. Rather, I intended to convey that the overall USDA inspection process is designed to appropriately examine and document all areas of care and treatment that are regulated by the Animal Welfare Act. An inspector might not examine each area of care and treatment, for all aspects of a facility, during a single inspection . . .

(ECF No. 38-5 ¶ 21.)

A *post-hoc* declaration that explains what Dr. Goldentyer meant to say in the Agency Denial is not background information; it is corrective. It does not merely explain the agency record so the court can better understand the basis of the Agency Denial. It changes material facts on which the Agency Denial is based. The Declaration does not clarify or illuminate the agency record; it is different from, and contradictory to, the Agency Denial. The doctor’s assertion that she did not “intend to convey” that a given inspection includes all AWA-covered areas, but rather that inspections, *in toto*, “are designed to” cover the “appropriate” areas is belied by the Agency Denial’s use of the singular “the inspector” and the conjunctive “and records”: “**The inspector** also observes the regulated animals; inspects facilities, including enclosure or housing materials space, **and** records.” (USDA Annual Inspections Document, ECF No. 39-1; emphasis added by the court.) The plain impression, if not the literal meaning, is that each inspector observes the animals, facility, and records during each inspection. And that, apparently, is untrue.

Adding to the linguistic basis for the court’s rejection of the Declaration, reference to Agency court filings in the companion FOIA suit mentioned above provides helpful, if not broader, context to the court’s rejection of Defendants’ argument that the Declaration provides mere explanatory background for the court’s assistance:

- APHIS issued the Agency Denial of Plaintiff’s Petition on October 10, 2019;
- On June 17, 2020, Plaintiffs issued their FOIA request for Agency records;
- Approximately five months later, Plaintiffs sued the Agency for failure to comply with FOIA (*see n.5, supra*);
- Three days later, on October 19, 2020, the Agency filed its Motion to Dismiss the instant action, which relied on and attached the Agency Denial (ECF 7-2) to argue Plaintiffs lack a cognizable injury – and specifically cited the very passage the Goldentyer Declaration now seeks to “clarify” by explaining what APHIS “intended to convey” in the Agency Denial;
- On March 18, 2021, in the midst of settling the FOIA action – which included production of the non-public USDA Annual Inspections Document, the Agency filed a Notice advising that “it is necessary to correct” Defendants’ statements to this court in their Motion to Dismiss “to the extent it suggests that every agency inspection covers ‘all areas’ of a facility.” (ECF No. 19; Civil Case No. 20-3013, D. Md. 2020.)

The Notice at ECF No. 19 goes on to explain to the court for the first time that “when conducting some types of USDA inspections – including ‘focused inspections’ – USDA may not ‘examine and document all areas of care and treatment that are covered under the [Animal Welfare Act].’ In light of this clarification, USDA no longer intends to rely on the statements it made in its motion to dismiss filings to the extent they suggest that each and every USDA inspection looks at all aspects of a regulated entity’s case and handling of animals.” (ECF No. 19.)

Inasmuch as revelation of the Agency's actual inspection practices – brought to light upon Plaintiffs' FOIA suit and the Agency's first-time publication of the internal USDA Annual Inspections Document – compelled officers of the court to issue what can only be viewed as a retraction to avoid apparent endorsement of the Agency's misstatements to the court, the Agency's effort here to persuade the court that Dr. Goldentyer's Declaration can live peaceably alongside the Agency Denial as a mere explanatory aid is rather beyond the pale.

Moreover, inasmuch as the Agency Denial was issued before the USDA Annual Inspections Document was made public – which is to say before Plaintiffs knew about the focused inspections practice – suggestion that a reader of the Agency Denial would somehow appreciate that the Agency did not “intend to convey” that all AWA-covered areas of care and treatment are inspected at each inspection when it said “[t]hey examine and document all areas of care and treatment that are covered under the AWA, including the plan” approaches absurd.

The Goldentyer Declaration is precisely the sort of after-the-fact cleansing of an agency record that the law prohibits the court to consider on judicial review. Therefore, the court will not consider the Declaration to amplify or support the Agency's denial of the Petition. The court may, however, consider the Declaration “for the limited purposes of ascertaining whether the agency considered all the relevant factors or fully explicated its course of conduct or grounds of decision.” *Asarco*, 616 F.2d at 1160.

Dr. Goldentyer's Declaration supports the court's conclusion that the Agency did not provide a full explanation for its reasoning, but rather based its Petition denial on facts known by it to be false. While the Agency's decision to deny the Petition need only be reasoned, surely, it must be truthful. Moreover, the Declaration establishes to the court's satisfaction that the Agency did not consider “all the relevant factors” when it denied the Petition. Because mandatory focused

inspections turn a blind eye to the constellation of considerations AWA requires the Agency to consider, the Agency clearly ignored and failed to consider “all the relevant factors” when concluding that the current AWA standards adequately fulfill the Agency’s statutory mandate.

The reader will recall that AWA, as amended by ISLAA, requires the USDA to promulgate standards that “include minimum requirements . . . for a physical environment adequate to promote the psychological well-being of primates.” 7 U.S.C. § 2143(a)(2)(B). ISLAA further provides that: “[t]he Secretary shall require each research facility to show upon inspection, and to report at least annually, that the provisions of this Act [7 USCS §§ 2131, *et seq.*] are being followed and that professionally acceptable standards governing the care, treatment, and use of animals are being followed by the research facility during actual research or experimentation.” *Id.* § 2143(a)(7)(A). With respect to investigations and inspections involving research facilities, “[t]he Secretary shall inspect each research facility at least once each year and, in the case of deficiencies or deviations from the standards promulgated under this Act, shall conduct such follow-up inspections as may be necessary until all deficiencies or deviations from such standards are corrected.” *Id.* § 2146(a). *See*, Section II(A)(1) and (2), *supra*.

While Defendants maintain that “the USDA provided a detailed explanation of why the agency believed that existing regulations were sufficient under the Animal Welfare Act, and accordingly why Plaintiffs’ requested changes to USDA regulations were unnecessary,” the decision was arbitrary and capricious because the Agency “relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency” *Motor Vehicle Mfrs. Ass’n. of U.S., Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

The Agency relied on factors Congress did not intend it to consider in constructing and implementing “focused inspections” – which, in turn, served as a basis for the Agency’s conclusion that the current USDA standard is adequate to fulfill its legislative charge. According to the USDA Annual Inspections Document, Agency “focused inspections” were developed to take the place of full annual inspections for AAALAC-accredited facilities “in response to concerns from inspectors about workload” (ECF No. 39-1.) The language of AWA makes plain that Congress enacted the statute to protect the welfare of animals in laboratory and research settings. The court is unconvinced that Congress intended the Agency to consider inspector workload as a factor when developing standards and protocols for protecting the welfare of animals. And while inspector workload may well be a practical consideration that may affect the Agency’s ability to fulfill congressional intent to protect the welfare of animals, the court rejects the notion that substituting a severely abridged version of proper, full annual inspections is consistent with AWA’s expression of congressional intent to protect the welfare of animals in research settings.

Likewise, the Agency has clearly failed to consider an “important aspect of the problem” by conducting focused inspections. According to the USDA Annual Inspections Document, during a focused inspection, an inspector may, for example, look only at records and not the animals, their environs, or the facilities at large; and the animals (or any one of these inspection items) may not be observed for years at a time. Therefore, the practice of focused inspections, by definition, fails to consider basic features essential to safeguarding animal welfare in a research setting – starting with the animals. Without conducting full inspections as required by 7 U.S.C. § 2143(a)(7)(A), the Agency lacks the necessary information to determine whether there is a problem regarding the welfare of nonhuman primates, or whether the existing standards are sufficient to meet the needs of the animals in research facilities in accordance with AWA.

AWA, as amended by ISLAA, mandates that the Agency create and maintain standards to “promote the psychological well-being of primates” by requiring “each research facility to show upon inspection, and to report at least annually, that” AWA is being followed and that professionally acceptable standards governing the care, treatment, and use of animals” are abided “during actual research or experimentation.” In order to do this, AWA requires the Agency to “inspect each research facility at least once each year and, in the case of deficiencies or deviations from the standards promulgated under this Act, shall conduct such follow-up inspections as may be necessary until all deficiencies or deviations from such standards are corrected.” 7 USCS §§ 2131, *et seq.* The practice of annual focused inspections in lieu of annual standard inspections deprives the Agency of basic, essential information about a facility’s standards in place “during actual research or experimentation” such that an inspector cannot know whether a facility deviates from “the standards promulgated under” AWA. Therefore, in denying the Petition on the basis that current inspection practices fulfill AWA, the Agency failed to consider an “important aspect of the problem.”

B. Public Comments and Attendant/Related Scientific Evidence

Further, the Agency Denial is not only contrary to the Agency’s internal record, the Agency Denial runs counter to the evidence or information developed through the public comment process of the Petition, as well as the science documented within the Petition and the comments. In the absence of information the Agency was required to gather and consider through standard annual inspections (and on which the Agency Denial incorrectly asserted it was based), the Agency had before it thousands of scientific community (and other) comments describing the suffering of nonhuman animals, including nonhuman primates, in research facilities. Had the Agency conducted full investigations as represented in the Agency Denial, the court’s scrutiny of the

Agency in this aspect would likely quietly conclude, in deference to agency discretion based on its own record. Stated differently, if the Agency considered the public comments and weighed them against the Agency's own record of facts and information developed through its proper inspection process, and provided a truthful, reasoned explanation for its decision, the court would yield to the Agency's expertise and discretion. In the absence of Agency evidence as represented in the Agency Denial (and as required by AWA), however, the Agency Denial runs counter to the evidence before it without reasoned, truthful explanation. In this manner, the Agency denied the Petition absent a factual basis on which to base its decision.

The Agency's apparent failure to consider any of the more than 10,000 public comments on the Petition is also contrary to the Agency's earlier (pre-denial) publication of the Petition in the Federal Register for public comment. As the Agency then acknowledged, the concerns and issues raised in the Petition "are important and that many parties will have an interest." Similarly, the Agency assured Plaintiffs that it would render its decision on the Petition once it had "analyzed all of the comments." Perhaps more disconcerting is the Agency's empty assurance to the public: "We are making this petition available to the public and soliciting comments regarding the petition and any issues raised by the petition that we should take into account as we consider this petition." 80 Fed. Reg. 24840, 24840 (May 1, 2015).

In the view of the Agency's express public admission (indeed, assurance) that public comments are relevant to its Petition decision-making process (which is quite separate from its statutory obligation to publish the Petition for public consideration under 5 U.S.C. § 553), the Agency's failure to address even one comment (or one category of comment) in its denial adds heft to the court's conclusion that the Agency did not consider evidence relevant to the subject matter it was tasked with deciding, that it failed to offer a plausible, reasoned explanation of how

it considered relevant public comments, and/or that it failed to explain the basis for its conclusion that there were no relevant public comments. 5 U.S.C. § 553; *see also*, *Home Box Office v. FCC*, 567 F.2d 9, 35-36 (D.C. Cir. 1977) (holding that “the opportunity to comment is meaningless unless the agency responds to significant points raised by the public.”)

The court is mindful that within the arbitrary and capricious review setting, “only comments which, if true, raise points relevant to the agency's decision and which, if adopted, would require a change in an agency’s proposed rule cast doubt on the reasonableness of a position taken by the agency. Moreover, comments which themselves are purely speculative and do not disclose the factual or policy basis on which they rest require no response.” *Id.* at 35 n.58. The Agency’s failure to articulate anything about the public comments (other than that they exist and were “reviewed”), however, fails to live up even to this relatively low bar. The court is left to understand that the Agency considered not one public comment to be relevant. Given the throngs of scientific community members’ interest in the subject and considerable, apparently serious-minded contributions from the relevant scientific community, it strains credulity that none of the 10,137 comments warranted even the barest of consideration. The Agency’s argument that advising Plaintiffs in the Agency Denial that it “reviewed every comment” is all that is required because the law does not require the Agency to “specifically address any particular comment in its explanation of the denial” misses the mark. (ECF No. 38-1 at 29.) The Agency is correct that it is not obligated to specifically address any particular comment in the Agency Denial, but neither is the Agency free to categorically ignore them. That the Agency “reviewed” the comments says nothing whatsoever as to the treatment they received in the decision-making process. And while the standard does not require detailed exposition on this front, it does require a modicum of content.

As the Supreme Court concluded in *State Farm*:

“There are no findings and no analysis here to justify the choice made, no indication of the basis on which the [agency] exercised its expert discretion. We are not prepared to and the Administrative Procedure Act will not permit us to accept such . . . practice. . . . Expert discretion is the lifeblood of the administrative process, but ‘unless we make the requirements for administrative action strict and demanding, expertise, the strength of modern government, can become a monster which rules with no practical limits on its discretion.’ *New York v. United States*, 342 U.S. 882, 884 [72 S.Ct. 152, 153, 96 L.Ed. 662] (dissenting opinion). (footnote omitted).”

Motor Vehicle Mfrs. Ass’n. of U.S., Inc. v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 48 (1983) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 167 (1962)).

C. Non-Binding Suggestions

Plaintiffs’ Petition complains that the Agency’s current standards intended to “promote the psychological well-being of primates” in research settings, as required by AWA, are outdated and too vague to be meaningfully enforceable. Plaintiffs argue in their Motion that the Agency Denial’s reliance on “non-binding suggestions” for its refusal to update its standards provides another basis on which the court should conclude that the Agency’s Denial was arbitrary and capricious. (ECF No. 35-1 at 22-23.)

In answer to Plaintiffs’ charge that the current standards prevent meaningful regulation of the psychological well-being of nonhuman primates used in research, the Agency Denial asserts, “such standards are, in fact, enforceable” as demonstrated by the fact that (1) between 2007 and 2015, 161 noncompliance citations were issued “involving 9 C.F.R. § 3.81;”¹⁰ (2) in 2017, the USDA offered an educational “symposium open to all interested parties” on “Practical Solutions to Welfare Challenges;” (3) between 2016 and 2018, the Agency “documented roughly 14 noncompliant findings . . . involving 9 C.F.R. § 3.81;” and (4) in 2018, the Agency offered eight “Animal Care Aids based on scientific literature.” (Agency Denial, ECF No. 38-4, at 2.)

¹⁰ 9 C.F.R. § 3.81 pertains to “[e]nvironment enhancement to promote psychological well-being.”

The Agency fails to state in its denial of the Petition, how many research facilities participated or attended the non-mandatory 2017 symposium or how many non-compliant facilities actually looked at, no less implemented, the Animal Care Aids. The court means not to criticize or diminish these Agency endeavors, but rather to draw out the logical disconnect between offering non-mandatory, non-binding educational tools and concluding that the Agency regulation standards are therefore meaningfully enforceable. Further the fact that Agency inspectors issued citations during a given period of time suffers from the same dissonance. This flawed logic is considerably magnified in the presence of the focused inspection protocol – which the Agency kept as “Internal Use Only” information.

Defendants counter that “the guidance provided in those sources are only a means to help regulated entities meet the performance standard set by Section 3.81, which requires . . . a plan that is ‘adequate to promote the psychological well-being of primates.’” Defendants offer that the standard set forth in Section 3.81 is the “binding requirement that all regulated entities are legally obligated to meet.” (ECF No. 38-1 at 25.) As discussed above, however, inasmuch as the Agency has fairly abdicated the full scope of its inspection obligations, the Agency’s reliance on “guidance provided by” non-mandatory educational tools comes up far short of providing the foundation necessary to justify its unequivocal conclusion the current standards “are, in fact, enforceable.”

Further, reliance on pre-2019 noncompliance citations fails to account for the Agency’s February 2019 procedural update prohibiting full annual inspections of AAALAC-accredited facilities. *See Flyers Rights Educ. Fund, Inc. v. FAA*, 864 F.3d 738, 745 (D.C. Cir. 2017) (concluding that the administration overlooked that the studies conducted were outdated and the agency’s reasoning “must adapt as the critical facts change”); *see also Am. Horse Prot. Ass’n v. Lyng*, 812 F.2d 1, 5 (D.C. Cir. 1987) (explaining that “a refusal to initiate a rulemaking naturally

sets off a special alert when a petition has sought modification of a rule on the basis of a radical change in its factual premises”).

Therefore, even assuming the Agency is correct that issuance of a certain number of noncompliance citations and educational offerings demonstrate (or tend to demonstrate) that AWA-compliance standards are enforceable, the Agency overlooked its actual, considerably withered, inspection protocols in place at the time of its denial of the Petition. The Agency Denial was therefore based on outdated information rendering its conclusion – that the current standards are enforceable and not in need of updating – arbitrary and capricious.

D. Action by the NIH

Plaintiffs argue that “the agency’s denial of Plaintiffs’ petition was also arbitrary and capricious because the USDA conspicuously failed to address the fact that NIH had necessarily determined that the AWA standard regarding the psychological well-being of primates was inadequate to ensure the psychological well-being of chimpanzees—the only primate species that agency addressed.” (ECF No. 35-1 at 27.) Defendants counter Plaintiffs “forfeited” this argument because Plaintiffs did not raise it in the Petition and, in any event, it misconstrues the Agency’s obligation vis-à-vis “other Federal departments.” (ECF No. 38-1 at 30; citing 7 U.S.C. § 2145(a).) While Plaintiffs’ Petition does not expressly state that NIH viewed existing regulations as insufficient, Plaintiffs plainly rely on the new NIH recommendations throughout their Petition as demonstration that a sister agency felt it necessary to implement more specific guidelines after considering the relevant scientific evidence and expertise. The court therefore disagrees that Plaintiffs’ forfeited or failed to raise this argument in their Petition. The court, however, finds Plaintiffs’ argument on this issue unavailing under the arbitrary and capricious standard. The Agency was not required to consult with NIH in this process, as the Agency was not establishing

standards or issuing regulations. 7 U.S.C. § 2145. Further, that the NIH concluded that the current AWA standard is inadequate is surely persuasive on the issue but is not, to the court's way of viewing it, itself primary evidence of same such that the Agency's failure to explain why it elected not to follow suit runs afoul of its obligations in considering and denying the Petition.

V. CONCLUSION

For the reasons set forth herein, by separate accompanying order, the court grants Plaintiffs' Motion at ECF No. 35, denies Defendants' Motion at ECF No. 38, and remands this action for Agency consideration of Plaintiffs' Petition consistent with this opinion.

/S/

Julie R. Rubin
United States District Judge

March 23, 2023